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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,427	12/12/2001	Harshal P. Bhagwatwar	U 013528-7	2278

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,427	BHAGWATWAR ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72-97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114 and extension of time, amendment and remarks, all filed 05/25/05. New claims 72-97 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 05/25/05 has been entered.

Claim Rejections - 35 USC § 112/New Matter

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 72-97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' remarks of 05/25/05 indicate that support for claim 72 is found inter alia in the last three lines on page 3 to the first two lines on page 4 in paragraphs [00014], [00033],

[00034], [00039], [00057], 00058] and [00078]. However, there is no disclosure for "water-insoluble surfactant" in the specification as originally filed. Paragraphs [00014], [00033], [00034], [00039], [00057], 00058] and [00078] do not provide support for "water-insoluble surfactant".

4. Claims 94 and 95 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating health disorder, does not reasonably provide enablement for preventing or prophylactic treatment of health disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The scope of enablement provided to one skilled in the art by the disclosure is treatment and is not commensurate with the scope of protection sought by the claims, which is claim to preventing/prevention/prophylaxis of health disorder. (See AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003); In re Moore, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003).

The issue is a scope of enablement issue in light of the high standards required for preventing. The specification does not provides examples, tested examples in large populations where health disorders have been kept from happening or occurring. There is no composition that has the ability of keeping all health disorders from happening.

The other question is: applicants claim to keep from happening health disorder, what health disorder is encompassed by the broad term of "health disorder"? Is the claimed invention directed to treating all health disorder or every health disorder?

Claim Objections

5. Claims 91, 92, 94 and 95 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 72-75, 82, 84, 91, 93, 94, 96 and 97 are rejected under 35 U.S.C. 102(b) as being anticipated by Anastasiu et al. (RO 79581).

Anastasiu discloses the delivery of vaccine from a delivery composition/system that comprises emulsifier in the oily phase and collagen and antigen in the aqueous phase (Title and English abstract). Collagen is one of the polymers recited in claim 75 and vaccine is one of the drugs in claim 82. The continuous hydrophobic gelled matrix is formed by dissolving emulsifier in the oily phase. The broad claims read on Anastasiu.

8. Claims 72-77, 79-83 and 91-97 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaleta et al. (US 5,618,522).

Kaleta discloses oil-in-water emulsion where the oil-phase and the aqueous phase may both contain emulsifier and the emulsifier content is not zero at all times (abstract; column 2, lines 3-5; and claim 1). The oil phase is thickened (column 2, lines 6-21); the thickener is selected from treated silica, silica, polymethacrylate and styrene copolymer, calcium stearate (column 3, 1-7) and sorbitan monostearate is one of the emulsifiers present in the oil phase (column 8, lines 15-40; claims 8 and 9) ; 40-95% of the composition is the aqueous phase and the aqueous phase contains water and water miscible solvents (column 8, lines 43-63), humectant or moisturizing agents selected from guanidine and one or mixtures from glycolic and glycolate salts, glycerol, polyethylene glycol, hyaluronic acid, sugars, starches and sorbitol (column 9, lines 1-12); NSAID's (column 10, lines 50-65) and anti-acne actives (column 10, lines 31-41) are also contained in the aqueous phase. The aqueous phase moisturizer is one of steareth 21, polyethylene glycol 60 sorbitan monostearate and others as listed on column 9, lines 31-51. Claim 72 is a composition claim and claims 96 and 97 are directed to the mechanism of delivery of the composition and the mechanism of delivery of the composition does not have patentable weight in the composition claim. Kaleta meets the limitation of the claims.

9. Claims 72-77, 79-82, 84, 91, 96 and 97 are rejected under 35 U.S.C. 102(b) as being anticipated by Tominaga (US 5,747,049).

Tominaga discloses composition that is intended for cosmetic, pharmaceutical and non-medical applications (column 7, lines 34-36); the composition comprises a variety of vehicles as

disclosed in column 7, line 49 to column 11, line 16; in Formulation Example 2, **oily phase** obtained by heat melting cetostearyl alcohol, squalane, molasses, hydrogenated lanolin, ethyl p-hydroxybenzoate, polyoxyethylene sorbitan monopalmitate, glycerol monostearate, sodium N-stearoylglutamate, 4-methoxy-4'-t-butyldibenzoylmethane, octyl methoxycinnamate, retinol acetate, evening primrose oil, and perfume was added to an aqueous phase that containing 2-aminoethylsulfinic acid, 1,3-butylene glycol, and polyethylene glycol 1500. See also Formulation Examples 3-6. The composition may also contain anti-inflammatory agents such as glycyrrhizic and salicylic acid derivative (column 6, lines 41-46). Polyethylene glycol is claimed in claim 75. Avocado oil, tubaki oil, evening primrose oil, Turtle oil, Macadamia nut oil, corn oil, mink oil, olive oil, rape oil, egg yolk oil, sesame oil, persic oil (apricot kernel oil), wheat germ oil, sasanqua oil, castor oil, linseed oil, safflower oil, cotton seed oil, perilla oil, soybean oil, peanut oil, tea seed oil, kaya (Torreya nucifera) oil, rice bran oil, Chinese tung oil, Japanese tung oil, jojoba oil, germ oil, triglycerides (e.g., glycerol trioctanoate and glycerol triisopalmitate); fats, such as cacao fat, coconut oil, horse fat, hardened coconut oil, palm oil, beef tallow, mutton tallow, hardened beef tallow, palm kernel oil, lard, beef bone fat, haze (Rhus succedancea L.) kernel oil, hardened oil, beef foot oil, Japan wax, and hardened castor oil; waxes, such as molasses, candelilla wax, cotton wax, carnauba wax, bayberry wax, cera ibota, whale wax, montan wax, rice bran wax, lanolin, kapok wax, lanolin acetate, liquid lanolin, sugar cane wax, lanolin fatty acid isopropyl ester, hexyl laurate, hydrogenated lanolin, jojoba wax, hard lanolin and Shellac wax are some of the oils/waxes that can be used in Tominaga's formulation (column 7, line 52 to column 8 line 4). Claim 72 is a composition claim and claims 96 and 97 are directed to the mechanism of delivery of the composition and the mechanism of

delivery of the composition does not have patentable weight in the composition claim. Tominaga meets the limitations of the claims.

10. Claims 72-77, 80, 82, 90-92, 93, 94, 96 and 97 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehta et al. (US 6,841,539).

Mehta discloses compositions and method to enhance topical delivery of oligonucleotides/nucleic acid (abstract; column 1, line 66); the compositions are in the form of emulsions including microemulsions and creams (column 2, lines 24 and 25); the compositions contain nucleic acids (column 2, line 28). In Mehta, the aqueous phase typically contains water, aqueous solution of the drug, glycerol, PEG, polyglycerols and propylene glycols (column 9, lines 1-4); the oil phase typically contains captex 300, Captex 355, Capmul MCM, fatty acid esters, medium chain (C8-C12) mono, di, and tri-glycerides, polyoxyethylated glyceryl fatty acid esters, fatty alcohols, polyglycolized glycerides, saturated polyglycolized C8-C10 glycerides, vegetable oils and silicone oil (column 9, lines 4-9). In Example 6, the oil phase contains isopropyl myristate and glycerol monostearate and the aqueous phase contains water and polyoxyl-40-stearate and the particles resulting from homogenization of the mixture of the oil and aqueous phases has a mean diameter of 1.0 μm (column 38, lines 58-67). In Example 7, the oil phase contains methylparaben, propylparaben, phenoxyethanol, glycerol monostearate and isopropyl myristate and the oil phase is added to the aqueous phase. The continuous phase of claim 72, which is the aqueous phase, permits the presence of surfactant or emulsifier because the phase is "comprising." Claim 72 is a composition claim and claims 96 and 97 are directed to the mechanism of delivery of the composition and the mechanism of delivery of the

composition does not have patentable weight in the composition claim. 1 μm is less than 100 μm in size. Mehta meets the limitations of the claims.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 88 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al. (US 6,841,539).

Mehta is discussed above. Mehta discloses a composition that contains emulsifier in the oil phase continuous phase and polymer in the aqueous discontinuous phase. However, the particles formed are 1 μm in diameter differing from the instant particles having sizes ranging from 1-400 μm. Differences in size of the particles will not patentably distinguish the instant claims over the prior art in the absence of a showing that the recited particles sizes provide unusual and unexpected results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the emulsion of Mehta where the particle size is 1 mm. In the absence of a showing, the particle size recited is not inventive over the particles of the prior art.

13. Claims 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al. (US 6,841,539).

Mehta is discussed above. Mehta discloses a composition that contains emulsifier in the oil phase continuous phase and polymer in the aqueous discontinuous phase. Mehta is silent on

the shape of the particles. Regarding the concentration of the polymer in the organic phase, and the concentration of the emulsifier, it is noted that differences in concentration will not support patentability of the subject matter over the prior art unless there is evidence indicating such concentration is critical (In re Aller). It would have been obvious to one of ordinary skill in the art at the time the invention was made to emulsion of Mehta according to the process of Mehta with the expectation of forming particles having diameter of 1 μm. It would be reasonable to expect that the particles so formed would have a specific structural definition of ranging from defined shape of spherical, oblong, elliptical to irregularly shaped particle.

14. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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